Investor Relations - SWK Holdings

Veru Announces Successful Bioavailability and Bioequivalence Clinical Trial for Tadalafil and Finasteride Combination Tablet for Benign Prostatic Hyperplasia

Company Plans to Submit NDA in 2019

MIAMI, Jan. 14, 2019 (GLOBE NEWSWIRE) — Veru Inc. (NASDAQ: VERU), an oncology and urology biopharmaceutical company, today announced that the clinical trial of the Company's proprietary Tadalafil and Finasteride Combination tablet met the U.S. Food and Drug Administration's (FDA) requirements for bioavailability and bioequivalence for the co-administration of tadalafil 5mg and finasteride 5mg dosed daily for benign prostatic hyperplasia (BPH) (Tad-Fin Combination Tablet).

Stability testing of commercially manufactured batches (GMP) of the Tad-Fin Combination Tablet required for submission of a New Drug Application (NDA) is in progress.

The Company has also requested a Pre-NDA meeting with FDA and anticipates submitting an NDA under the 505(b)(2) regulatory pathway in the second half of calendar year 2019.

Tad-Fin Combination Tablet combines two of the most popular medicines, tadalafil and finasteride, that are currently prescribed separately to treat lower urinary tract symptoms caused by an enlarged prostate also known as BPH. The co-administration of tadalafil and finasteride has been shown clinically to be more efficacious in treating BPH symptoms than either tadalafil or finasteride alone.* Our Tad-Fin Combination Tablet is proprietary and is designed to improve patient compliance and safety.

According to current FDA approved labeling, Tadalafil (CIALIS®) (PDE5 inhibitor) is approved to treat both BPH and erectile dysfunction, and Finasteride (PROSCAR®) (5 alpha-reductase inhibitor) is approved to treat symptoms of BPH, prevent the progression of BPH, reduce the risk of acute urinary retention and decrease the potential need for prostate surgery. Finasteride (PROPECIA®) is also approved to treat male pattern hair loss.

"This successful clinical study for Tad-Fin Combination Tablet will allow Veru to rely on the safety and efficacy of PROSCAR and CIALIS for BPH in the FDA approval process without the requirement of a large clinical trial. This is an exciting milestone for Veru as the Tad-Fin Combination Tablet is our lead proprietary urology pharmaceutical medicine and the first drug for which we plan to submit an NDA to FDA later this year. We plan to use anticipated cash flow from sales of our urology specialty pharmaceuticals, like Tad-Fin Combination Tablet, to invest in our prostate cancer programs and to execute on our strategy to become the leading pharmaceutical company in providing products for the continuum of care for prostate cancer, said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. "We believe our Tad-Fin Combination Tablet will be an attractive product for the multi-billion-dollar global market for BPH and substantially increase compliance and safety in men who suffer from BPH or BPH and erectile dysfunction."

About Veru Inc.
Veru Inc. is an oncology and urology biopharmaceutical company developing novel urology specialty pharmaceuticals and medicines for the prostate cancer continuum of care. The Veru prostate cancer pipeline includes zuclomiphene citrate (also known as VERU-944, *cis*-clomiphene) and VERU-111 (bisindole). Zuclomiphene citrate is an estrogen receptor agonist being evaluated in a Phase 2 trial to treat hot flashes, a common side effect caused by hormone treatment for men with advanced prostate cancer. VERU-111 is an oral, next-generation, first-in-class selective small molecule that targets and disrupts alpha and beta subunits of microtubules in cells to treat metastatic prostate cancer patients whose disease is resistant to both castration and novel androgen blocking agent (abiraterone or enzalutamide) therapies. Veru expects to enroll the first patient in the VERU-111 Phase 1b/2 clinical trial in January 2019.

Veru is also advancing new drug formulations in its specialty pharmaceutical pipeline addressing unmet medical needs in urology. Tamsulosin DRS granules and Tamsulosin XR capsules are formulations of tamsulosin, the active ingredient in FLOMAX®, which Veru has developed to avoid the "food effect" inherent in currently marketed formulations of the drug, allowing for potentially safer administration and improved patient compliance (NDA submission expected in 2019). Veru is also developing Tadalafil/Finasteride combination tablet. Tadalafil (CIALIS®) is currently approved for treatment of BPH and erectile dysfunction and finasteride (PROSCAR® and PROPECIA®) is currently approved for treatment BPH and male pattern hair loss. The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than either drug alone*(NDA submission expected in 2019).

Veru's Female Health Company Division markets the FC2 Female Condom / FC2 Internal Condom®, an FDA-approved product for the dual prevention of unwanted pregnancy and sexually transmitted infections, and the PREBOOST® medicated individual wipe for the prevention of premature ejaculation. The FC2 Female Condom / FC2 Internal Condom is marketed commercially and in the public health sector both in the U.S. and globally.

FC2 is available by prescription in the U.S. including through the virtual doctor smartphone app “HeyDoctor” at www.fc2.us.com. FC2 improves the lives, health and well-being of women around the world. For PREBOOST® Veru has a co-promotion and distribution agreement with Timm Medical Technologies, Inc., a specialty urology sales organization, and the Company also recently entered into a US distributor agreement with a premier and fast-growing men’s health and telemedicine company that discreetly sells men’s health products via the internet. To learn more about these products please visit www.verupharma.com.

*Casabé A et al. Journal of Urology 191:727-733 2014

“Safe Harbor” statement under the Private Securities Litigation Reform Act of 1995:
The statements in this release that are not historical facts are “forward-looking statements” as that term is defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this release include statements relating to the regulatory pathway to secure FDA approval of the Company’s drug candidates, the anticipated timeframe for clinical studies, clinical study results and FDA submissions, and the potential for cash flow from the sales of urology specialty pharmaceuticals to support Company growth. Any forward-looking statements in this release are based upon the Company’s current plans and strategies and reflect the Company’s current assessment of the risks and uncertainties related to its business and are made as of the date of this release. The Company assumes no obligation to update any forward-looking statements contained in this release because of new information or future events, developments or circumstances. Such forward-looking statements are subject to known and unknown risks, uncertainties and assumptions, and if any such risks or uncertainties materialize or if any of the assumptions prove incorrect, our actual results could differ materially from those expressed or implied by such statements. Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, but are not limited to, the following: risks related to the development of the Company’s product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market; potential delays in the timing of and results from clinical trials and studies and the risk that such results will not support marketing approval and commercialization; potential delays in the timing of any submission to the FDA and regulatory approval of products under development; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; product demand and market acceptance; competition in the Company’s markets and the risk of new or existing competitors with greater resources and capabilities and new competitive product introductions; price erosion, both from competing products and increased government pricing pressures; manufacturing and quality control problems; compliance and regulatory matters, including costs and delays resulting from extensive governmental regulation, and effects of healthcare insurance and regulation, including reductions in reimbursement and coverage or reclassification of products; some of the Company’s products are in development and the Company may fail to successfully commercialize such products; risks related to intellectual property, including the uncertainty of obtaining patents, the effectiveness of the patents or other intellectual property protections and ability to enforce them against third parties, the uncertainty regarding patent coverages, the possibility of infringing a third party’s patents or other intellectual property rights, and licensing risks; government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay, restructuring or substantial delayed payments; a governmental tender award indicates acceptance of the bidder’s price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public sector customers may order and purchase fewer units than the full maximum tender amount or award; penalties and/or debarment for failure to satisfy tender awards; the Company’s reliance on its international partners and on the level of spending by country governments, global donors and other public health organizations in the global public sector; risks related to concentration of accounts receivable with our largest customers and the collection of those receivables; the economic and business environment and the impact of government pressures; risks involved in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers; the Company’s production capacity, efficiency and supply constraints and interruptions, including due to labor unrest or strikes; risks related to the costs and other effects of litigation, including product liability claims; the Company’s ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; the Company’s ability to successfully integrate acquired businesses, technologies or products; and other risks detailed in the Company’s press releases, shareholder communications and Securities and Exchange Commission filings, including the Company’s Form 10-K for the year ended September 30, 2018. These documents are available on the “SEC Filings” section of our website at www.verupharma.com/investors.

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